Original Article

Surgical Outcomes of Trabeculotomy in Newborns with Primary Congenital Glaucoma

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Abstract

Background: Early surgical intervention is required for the primary congenital glaucoma (PCG). There are currently few reports on the surgical outcomes in infants with PCG. This study aimed to evaluate the efficacy and safety of trabeculotomy and the postoperative visual outcomes in Chinese newborns with PCG within 4 weeks of birth.

Methods: A total of 21 eyes of 12 patients with PCG who underwent primary trabeculotomy within 4 weeks of birth were retrospectively studied. Preoperative and postoperative intraocular pressure (IOP), corneal clarity and diameter, axial length and optic disc cupping, visual acuity and postoperative refractive error, success rates, and complications were evaluated. Kaplan-Meier survival analysis was applied to evaluate the success rates.

Results: The mean follow-up time was 46.9 ± 34.4 months (range: 12–122 months). The postoperative IOP was significantly lower than the preoperative IOP at all of the follow-up visits ($P < 0.001$). The complete success rates for all eyes at 1, 2, 3, and 5 years postoperatively were 90.5%, 85.7%, 85.7%, and 85.7%, respectively. The IOPs of the three patients who needed antiglaucomatous medications postoperatively were also well controlled. At the last visit, the cornea became clear, and the cup-to-disc ratio decreased significantly ($P = 0.01$) although the horizontal corneal diameter did not change significantly ($P = 0.11$). Visual acuities were able to be recorded in eight eyes at the last visit, among which six eyes had a best-corrected visual acuity of 20/40 or better. There were no severe intraoperative or postoperative complications.

Conclusions: Trabeculotomy proves to be a safe and effective treatment in reducing IOP in this group of Chinese newborns with PCG. The outcomes of vision function were satisfactory in most of the patients.

Key words: Glaucoma; Primary; Congenital; Newborn; Trabeculotomy

Introduction

Primary congenital glaucoma (PCG) is the most common type of glaucoma in children, accounting for 2.5–15% of all documented cases of pediatric blindness.[1,2] The prevalence of PCG is variable in different populations and occurs in approximately 1 in 10,000 births.[2] The classic symptoms of PCG include epiphora, photophobia, and blepharospasm. Oftentimes, the condition will lead to increased intraocular pressure (IOP), opaque cornea, enlarged eyeball, damaged optic disc, and loss of visual function. Without timely treatment, individuals with PCG often face lifetime disability and decreased the quality of life. In China, there has been a delay in seeking treatment of PCG for the affected individuals because of financial difficulty or the lack of recognition of the disease.

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PCG is usually associated with a significant anatomic anomaly of the anterior drainage angle, and it responds poorly to medical therapy alone. In principle, early surgical intervention is crucial in the disease prognosis.[3] Previous studies have reported that goniotomy and trabeculotomy are the preferred initial surgical intervention for PCG.[4,5] The early literature suggested that the surgical prognosis of

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PCG was poor in children born with glaucoma.[6] Goniotomy is the most traditional surgical procedures, and its success rates in children born with glaucoma were only 25%.[6] Recently, Mandal *et al*.[7] reported satisfactory surgical outcomes in newborn with glaucoma undergoing combined trabeculotomy and trabeculectomy within 1 month of birth. However, no guidelines have been established in terms of the surgical options or timing for PCG. Because of the low incidence and neglected recognition of PCG, there have been few reports on the surgical outcomes in infants with PCG in China, especially those younger than 4 weeks of birth.

Successful management of PCG involves IOP control, as well as the restoration of visual function. The current study aimed to evaluate the long-term surgical outcome and postoperative visual acuity (VA) in Chinese infants with PCG who underwent trabeculotomy within 4 weeks of birth over a 10-year period.

Methods

Patient recruitment

Patients with PCG who underwent primary trabeculotomy in the Glaucoma Department of the Zhongshan Ophthalmic Center from April 2004 to February 2013 were consecutively enrolled. The inclusion criteria of the current study included: (1) A definite diagnosis of PCG, which was based on the presence of elevated IOP in association with at least one of the following findings, corneal haze with or without Haab's line, enlarged corneal diameter, increased axial length (AL), increased cup-to-disc (C/D) ratio of more than 0.3, or the presence of significant cupping asymmetry between the right and left eyes; and (2) underwent trabeculotomy as the initial surgical intervention for PCG within 4 weeks of birth. Patients who had significant systemic conditions or <1 year of follow-up postoperatively, or those whose Schlemm's canal could not be identified during the operation were excluded. The study was conducted with the approval of Hospital Ethics Committee at Sun Yat-sen University.

Examination and follow-up

Baseline examinations of all children were performed in the clinic to make a provisional diagnosis of PCG. The patient's condition was explained to the parents and consent was obtained for further examination under general anesthesia and for surgical intervention afterward. Ophthalmic examinations included IOP measurement, slit lamp examination, corneal clarity and diameter measurement, ocular biometry, direct ophthalmoscopy, postoperative VA, and refraction. During the follow-up period, ocular biometry was measured every 6 months.

IOP was measured with Schiötz tonometer (Suzhou Medical Instruments, Suzhou, China) by experienced technicians. The anterior segment was assessed using a hand-held slit lamp (Keeler, Bucks, England), and the horizontal corneal diameter was measured with a caliper. Ocular biometry was performed with A-scan ultrasound (Quantel Medical, CF, France) and AL was obtained. C/D ratio was evaluated by direct ophthalmoscopy (66 Vision, Suzhou, China) by experienced ophthalmologists. VA was assessed when possible using Snellen VA charts when children were above the age of 3 or when they were cooperative enough to complete the test. Best-corrected visual acuity (BCVA) was recorded when the vision was lower than the standard vision according to the age. Refraction was measured during the follow-up visits with complete cycloplegia, which was induced with 1% atropine (Zhongshan Ophthalmic Center, Guangzhou, China) in children younger than 7 years of age or with 0.5% tropicamide (Wujing, Wuhan, China) in those older than 7 years of age. When necessary, 10% chloral hydrate (0.7–0.8 ml/kg) was applied to patients for examinations.

After the surgery, all the patients were treated with topical 1% pilocarpine (Zhongshan Ophthalmic Center, Guangzhou, China), 1% Pred Forte (dexamethasone, Allergan, Parsippany-Troy Hills, NJ, USA) and ofloxacin eye drops (Santen, Japan) four times per day, and tobramycin and dexamethasone ophthalmic ointment (Qilu, China) at night for 4 weeks. The postoperative follow-up was scheduled at 1 week, 2 weeks, 1 month, 3 months, and every 3 months thereafter. The indication of applying antiglaucomatous eye drops (brinzolamide or prostaglandin) was an IOP >21 mmHg (1 mmHg = 0.133 kPa) in two consecutive follow-up visits or continuous corneal edema postoperatively. The numbers of antiglaucomatous eye drops used, as well as the intraoperative and postoperative complications, were recorded.

Surgical procedure

All surgeries were performed by a single glaucoma specialist (Xing Liu) using a standardized procedure similar to McPherson's maneuver:[8] After general anesthesia by propofol and fentanyl, and local anesthesia with a subconjunctival injection of 2% lidocaine, a fornix-based flap was formed on conjunctiva. A scleral flap 4 mm × 3 mm of three-quarters thickness was prepared at the 12 o'clock position. In the transition zone between the gray and white limbus was the scleral sulcus containing Schlemm's canal. A 1 mm radial incision was made, entering Schlemm's canal externally, and the incision was slowly deepened until the outer wall of Schlemm's canal was opened and a sleeping aqueous humor was seen. A trabeculotome was introduced into the canal, inserted to its full length and then swung gently into the anterior chamber to rupture the trabecular meshwork. The procedure was performed to the right with one trabeculotome and to the left with the fellow instrument. The trabecular meshwork was completely dissected at 120°. The scleral flap was replaced and sutured into place with three 10-0 nylon sutures. The conjunctival flap was also replaced and closed with 8-0 absorbable sutures.

Success criteria

The surgery was considered a complete success when the IOP was controlled under 21 mmHg with no progression of disc cupping or increase of corneal diameter. Qualified

success was defined when such pressure was maintained with topical antiglaucomatous medications. Failure was defined as IOP >21 mmHg with maximum medication, the requirement of a second operation to lower IOP, and the occurrence of severe complications such as endophthalmitis or suprachoroidal hemorrhage.

Statistical analysis

Data were expressed as a mean ± standard deviation (SD). The SPSS (version 20.0, SPSS, Chicago, IL, USA) software was used for the statistical analysis. The paired-samples Student's *t*-test was applied on the comparisons of the parameters, such as corneal diameter, AL, and C/D ratio. (The C/D ratio was compared only when it could be measured both preoperatively and postoperatively). Repeated measurement was applied on the IOPs changed, whereas the Fisher's exact test was applied on the comparisons of the number of antiglaucomatous drugs before and after operations. The cumulative probability of success was analyzed by Kaplan-Meier life-table analysis. $P < 0.05$ was considered as statistically significant.

Results

A total of 21 eyes of 12 patients were included in the study, among them four girls and eight boys. PCG was diagnosed unilaterally in three patients and bilaterally in nine patients. All the patients were presented at birth, and the mean age of surgery was 26.1 ± 3.9 days (range: 11–28 days). The average follow-up was 46.9 ± 34.4 months (range: 12–122 months) and the mean age at the last visit was 3. 7 ± 2.9 years (range: 1–10 years).

Before the surgical intervention, the average IOP was 29.9 ± 7.3 mmHg. The mean horizontal corneal diameter was 11.9 ± 0.9 mm and all 21 eyes showed corneal edema, with five cases of Haab's line. The C/D ratio was able to be evaluated in nine eyes, of which seven eyes were with C/D >0.3 or there was an asymmetric C/D ratio in both eyes. AL was obtained in all 21 eyes with a mean of 19.9 ± 0.9 mm [Table 1].

The postoperative IOPs were significantly lower than the preoperative IOPs at all of the follow-up visits [$P < 0.001$, Figure 1]. The C/D ratio decreased significantly ($P = 0.01$), while AL increased significantly ($P < 0.0001$) as measured at the last visit when six eyes were measured with an AL >25 mm. Although no significant change was found with the horizontal corneal diameter ($P = 0.11$), the cornea became clear after the operation [Table 1].

At the last follow-up visit, BCVA was successfully measured in eight eyes [Table 1]. Data regarding the refractive status were available for 17 eyes. For the remaining four eyes, refraction was not obtained because of corneal Haab's line. Refraction ranged from +2.5 to −12.0 diopters (D) and 14 of the eyes were myopic [Table 1].

The number of antiglaucomatous eye drops after the operation decreased significantly ($P < 0.001$). All of the patients needed 1–2 antiglaucomatous eye drops before the surgery. At the last follow-up, two eyes were on two antiglaucomatous eye drops and one eye was on one antiglaucomatous eye drop, whereas the remaining 18 eyes were free of antiglaucomatous drugs. The detailed postoperative measurements of these three cases are shown in Table 2. The preoperative IOP, corneal clarity and diameter, and AL of these three eyes showed no difference with others with complete surgical success ($P > 0.05$).

Complete success was obtained in 18 eyes, and qualified success was achieved in all 21 eyes. Kaplan-Meier survival analysis showed that the complete success rates at 1, 2, 3, and 5 years after operation were 90.5%, 85.7%, 85.7%, and 85.7%, respectively [Figure 2]. Meanwhile, the IOP of the three cases that needed antiglaucomatous medications postoperatively were also controlled under 21 mmHg. There was no failure case.

There was no severe intraoperative or postoperative complication. Hyphema was found in four eyes postoperatively, which resolved within 3 days after the operation. The surgical outcomes of these four eyes turned out to be completely successful. There was no incidence of shallow anterior chamber or choroidal detachment.

Discussion

Glaucoma during infancy is one of the leading causes of blindness in childhood.[9] The goal of preserving a lifetime of vision for these children involves early, prompt control of IOP, correction of ametropia, and rigorous amblyopia treatment.[10] In the current case series, the efficacy in terms of IOP control and the safety of trabeculotomy within 4 weeks of birth were evaluated in treating PCG. Satisfactory success rates were obtained, with relatively good VA outcome even at the 10-year follow-up mark.

Goniotomy and trabeculotomy are preferred as the initial surgical intervention for patients with PCG because of their effectiveness in reducing the IOP and their relatively low rate of serious complications.[4,5,11] The advantages of goniotomy are not to disturb the conjunctiva if filtering surgery is subsequently needed, but it requires a clear cornea to afford an adequate intraoperative view of the angle.[12,13] In the current study, all of the patients had corneal edema, which made goniotomy difficult to perform. The alternative surgical technique of trabeculotomy is possible even in the presence of severe corneal edema. Trabeculotomy is reported to be easier and more predictable than goniotomy in PCG.[8,14] Cai *et al*.[15] reported the success rate of trabeculotomy in 22 cases (33 eyes) with PCG in China of 97.0%, 93.2%, and 74.5% at the 1st, 3rd, and 5th year, respectively, the mean age of which was 46.6 ± 48.5 months (range: 12 days to 14 years). Yalvac *et al*.[4] reported the success rate of trabeculotomy in 24 cases (36 eyes) with congenital glaucoma in Turkey of 92.0%, 82%, and 74% at the 1st, 2nd, and 3rd year, respectively, of which the mean surgery age was 38.38 ± 11.77 months (range: 12–48 months). The success

Table 1: Ocular features of the newborns with primary congenital glaucoma before and after surgery

Demographics	Preoperative (n = 21)	Last visit (n = 21)	t	P
Horizontal corneal diameter (mm), mean ± SD	11.93 ± 0.91	11.79 ± 0.90	1.67	0.11
Corneal clarity, *n*				
Clear	0	21	N/A	N/A
Edema (mild, fundus seen)	9	0		
Edema (severe, fundus not seen)	12	0		
Scar	0	0		
Haab's line	5	5		
Cup-to-disc ratio, mean ± SD	0.53 ± 0.19	0.37 ± 0.24	3.33	0.01
Axial length (mm), mean ± SD	19.98 ± 0.98	23.52 ± 2.19	−7.63	<0.001
Best-corrected visual acuity, *n*				
≥20/40		6	N/A	N/A
20/40–20/60		1		
<20/60		1		
Refractive status, *n*				
Myopic (SE ≤−0.50 D)		14	N/A	N/A
Emmetropic (−0.50 D <SE <+0.50 D)		1		
Hyperopic (SE ≥+0.50 D)		2		

Data are presented as mean ± SD or *n*. *P*: Last visit group versus preoperative group; Cup-to-disc ratio was assessed in nine eyes preoperatively and 21 eyes postoperatively; Best-corrected visual acuity was measured in eight eyes postoperatively; Refractive status was measured in 17 eyes postoperatively; SE: Spherical equivalent; N/A: Not applicable; SD: Standard deviation; D: Diopters.

Table 2: Pre- and post-operative features of the three eyes needing antiglaucomatous drugs after trabeculotomy

Patients	Preoperative				Postoperative time point for IOP >21 (mmHg)	Last visit				Follow-up (months)
	IOP (mmHg)	Corneal diameter (mm)	Corneal edema	AL (mm)		IOP (mmHg)	Corneal clarity	Corneal diameter (mm)	AL (mm)	Medications number	
1	33.0	14	Severe	19.98	21 days (25.8)	17.2	Clear	14	26.02	2	28
2	30.4	11	Severe	18.30	2 years (25.8)	18.0	Clear	11	22.36	2	28
3	37.2	12	Severe	20.81	1 month (28.1)	17.2	Clear	12	21.78	1	13

"severe" means C/D ratio could not be measured; "postoperative time point for IOP >21 mmHg" means the highest IOP at follow-up period after operation. IOP: Intraocular pressure; AL: Axial length; C/D: Cup-to-disc; 1 mmHg = 0.133 kPa.

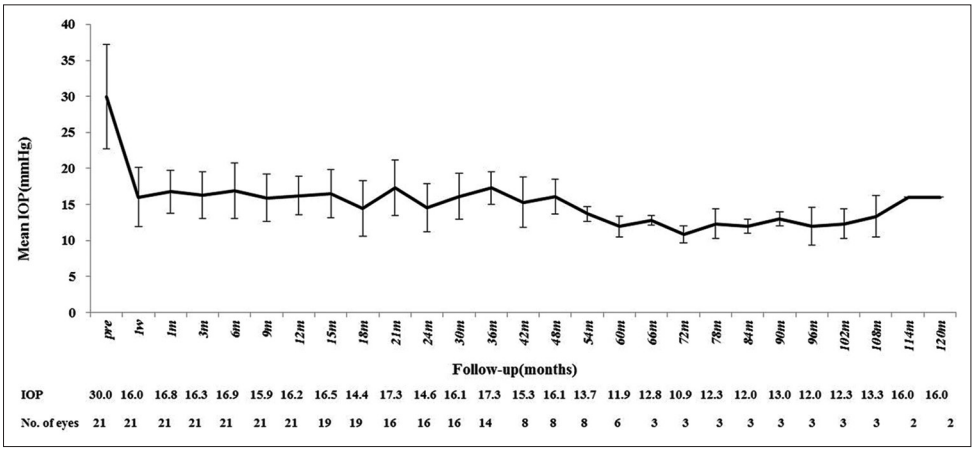

Figure 1: Mean and standard deviation of IOP (mmHg) changing from baseline to 10 years follow-up was represented as the curve. The postoperative IOPs were significantly lower than the preoperative IOPs at all of the follow-up time points (P < 0.001). IOP: Intraocular pressure.

criteria of these two studies were IOP control of <21 mmHg with topical antiglaucomatous drugs postoperatively. In addition, the age of operation of the above two studies was older than 1 month of age.

It has been established in the literature that an early timing for surgery is crucial in the prognosis of PCG.[4,8] Mandal *et al*.[7] reported a satisfactory surgical outcome on 25 cases (47 eyes) with newborn glaucoma (twenty cases of

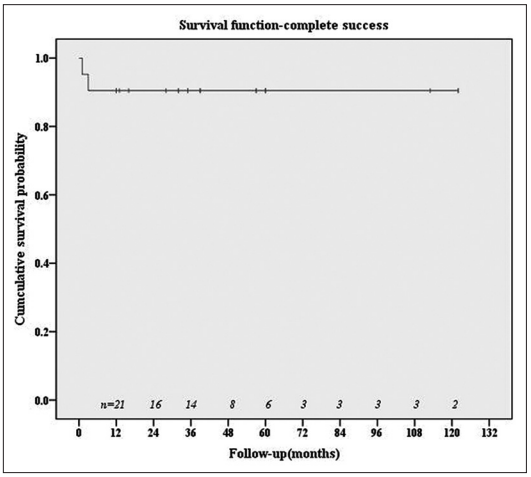

Figure 2: Kaplan-Meier survival curve showing the complete success rates in 21 eyes of 12 patients with PCG, who underwent primary trabeculotomy within 4 weeks of birth over 5 years of follow-up. The success rates declined over time, but an 85.7% success rate was maintained after the 2nd year. The letter *n* means the number of eyes in the follow-up period. PCG: Primary congenital glaucoma.

PCG and five cases of secondary developmental glaucoma) undergoing combined trabeculotomy and trabeculectomy within 1 month of age, with a success rate of 89.4%, 83.6%, and 71.7% at the 1st, 2nd, and 3rd years, respectively. Walton *et al.*[16] reported the success rate on 39 eyes with late-recognized PCG undergoing goniotomy between 1 and 2 years was better than that of between 2 and 4 years, and 2–4 years was better than that of older than 4 years. In the study, all of the patients were operated within 4 weeks of birth with satisfactory outcomes. This confirmed again that early diagnosis and prompt surgical intervention were the keys to successful treatment.

Other important clinical measurements should be taken into consideration for the prognosis of PCG, such as the preoperative corneal diameter, corneal clarity, and AL.[17] Al-Hazmi *et al.*[17] had reported that a better surgical outcome of trabeculotomy could be achieved when the preoperative corneal diameter was <13 mm and <1 year of age. Dietlein *et al.*[18] had shown that successful surgery was associated with an AL <24 mm at surgery age ranging from 0 to 50 months. In the current study, the mean corneal diameter of patients was 11.93 ± 0.91mm and the mean AL was 19.98 ± 0.98 mm before the operation, which might also be the factors to our high surgical success rate. On the three eyes that needed antiglaucomatous drugs after the operation, the corneal diameter of one case was 14 mm, and each of the three eyes had severe corneal edema before the operation. Although there were no statistical differences of the preoperative features between these three eyes and others with complete surgical success, a greater corneal diameter and worse corneal clarity might be the factors related to the failure of the surgery.

AL and C/D ratio are important measurements that should be observed in the follow-up period.[4] The C/D ratio significantly decreased in all of the cases at the last visit in our study. It had been reported by previous studies[4,19-22] that the C/D ratio was reversible after a successful surgery in congenital glaucoma. The results of our study confirmed that a decrease in the C/D ratio is an important indicator of a successful operation, especially in infants. There was a remarkably good correlation of postoperative IOP with postoperative AL growth, and change in AL was more important to evaluate than absolute AL.[23] In the current study, most of the AL growth (twenty eyes) was considered controlled according to the nomogram of AL growth proposed by Kiefer *et al.*,[23] and only one eye needed antiglaucomatous drugs postoperatively that was out of the normal AL growth. This suggested that the nomogram of AL growth proposed by Kiefer was a good way to evaluate the surgical outcome.

The final goal of treatment on congenital glaucoma is preserving or restoring the best possible visual function. However, precise VA measurements are difficult to obtain for infants. In the current study, VA could be recorded for eight eyes at the last visit, among which six eyes had a BCVA of 20/40 or better. Meanwhile, myopia was the most common refractive error, found in over 80% eyes at the last visit. In another study, only 5 out of 19 patients (26.3%) with congenital glaucoma operated within 1 month had BCVA of 20/40 or better,[7] and there were 21 myopic eyes out of 39 eyes at the last visit. The visual function in the current study was satisfactory and encouraging because all of the patients had an early operation within 4 weeks of birth and all of the patients had a clear cornea and normal IOP with or without antiglaucomatous drugs at the last visit. This suggests that early operation and successful surgical outcome led to good visual function in PCG. Moreover, attention should be paid to the refractive status of children in the follow-up period and should provide correction of ametropia and rigorous amblyopia treatment.

There were no severe intraoperative or postoperative complications in our study. Hyphema was the only complication that occurred, and it occurred in only four eyes (19%). The incidence of hyphema in our study was smaller than that in another report by Tamcelik and Ozkiris (27.4%).[24] All hemorrhage resolved within 3 days after the operation and had no effect on the success rate in our study.

There are several limitations in the current study. First, the study was limited by its retrospective design. Second, owing to the rarity of the included patients, the sample size was relatively small. Finally, postoperative VA data could not be recorded in two-thirds of patients because of the noncompliance of children in the examination.

In conclusion, the current study provides evidence that early trabeculotomy is safe and effective in treating newborns with PCG. Preoperative measurements such as corneal diameter and AL are likely to be associated with surgical outcomes. Further studies with larger sample size, longer follow-up period, and more comprehensive visual function evaluation

are warranted to investigate the long-term efficacy and safety of the intervention.

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Conflicts of interest

There are no conflicts of interest.

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